

Requirement For Restriction Under 35 U.S.C. § 121

In the restriction issued March 21, 2003, the pending claims were alleged to describe the following independent and district inventions:

- I. Claims 1-19, drawn to a method for treating a subject having an autoimmune disorder or inflammatory conditions; and
- II. Claims 20-22, drawn to a method of assaying for agents that treat cells or tissue involved in a pathology of autoimmune diseases and inflammatory conditions.

The Office argued that in the present case the different inventions have different effect since Group I relates to a method of treating medical disorders and Group II relates to assaying compounds. The Office stated that the inventions have acquired a separate status in the pharmaceutical art as can be seen from their different classifications. The Office argued that because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The Office stated that if Group I is elected, then the application contains claims directed to the following patentably distinct species of the claimed invention:

TREATMENT OF EACH OF THE FOLLOWING DISEASES:

- a. multiple sclerosis;
- b. Type I diabetes;
- c. glomerulonephritis systemic lupus erythematosus;
- d. rheumatoid arthritis;
- e. psoriatic arthritis;
- f. reactive arthritis;
- g. Sjogren's syndrome;
- h. graft-versus-host disease;
- i. muscular dystrophy;
- j. myasthenia gravis;
- k. atherosclerosis; and
- l. osteoarthritis.

Applicant was advised to select a single species and identify the claims that read on the species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Traversal of Requirement for Restriction

Applicant's undersigned attorney, on behalf of Applicant, elects Group I, claims 1-19, with traverse. Applicant further elects the single disclosed species of rheumatoid arthritis. Claims 1-13 and 16-19 read in the elected species. However, Applicant expressly reserves his right under 35 U.S.C. § 121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application, or an application claiming the benefit of this application under 35 U.S.C. § 120.

Applicant traverses the requirement and requests the Office to reconsider and withdraw the restriction requirement between the inventions of Groups I-II, claims 1-22. There are two criteria for a proper requirement for restrictions, namely, (1) the inventions must be independent or distinct, and (2) there must be a serious burden on the Examiner if restriction is not required. Under M.P.E.P. § 808, the Examiner must examine the subject application on the merits even though it includes claims to distinct inventions, if the search and examination of the application can be made without serious burden.

In the reasons for restriction, the Office alleged that the claims relate to two separate groups because two different method types are claimed: an assay method and a treatment method. Applicant agrees that two generic methods are claimed but point the Office to the overlap in the elements of the claims. Each claim is directed to the treatment of a chronic inflammatory disease or an autoimmune disease. Additionally, in view of the common element among claims 1 to 22, Applicant submits that a search of the art of references related to the invention of claims 1-19, would likewise uncover art related to the invention of claims 20-22. Therefore, it would not impose a serious burden on the Office to examine the inventions of Groups I to II at this time.

Accordingly, in view of the preceding discussion, Applicant respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject application between the inventions of Groups I and II. Therefore, restriction is not proper under 35 U.S.C. § 121 and withdrawal of this restriction is respectfully requested.

CONCLUSION

No additional fee is deemed necessary in connection with the filing of this Response. However, if the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-2518**, referencing billing number **2023896-7008412001**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

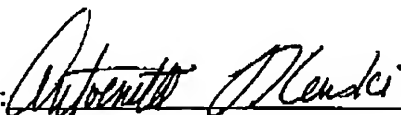
Should a telephone advance prosecution of the subject application, the Examiner is invited to contact the undersigned at (650) 849-4950.

DATE

April 18, 2003

Respectfully submitted,

By:



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